

REMARKS

Responsive to the Office Action mailed June 7, 1005 and with an extension of time of three months, the present pager is timely filed on or before December 7, 2005. Applicants acknowledge with gratitude the recitation in the Office Action that claims 1 -26 and 30 – 33 are allowed.

By the present Amendment, no claims are cancelled and claims numbered 31 (second occurrence as-filed), 32 and 33 are amended. Accordingly, renumbered claims 1 – 34 are in the Application. Entry of the amendments and reconsideration of the Application are respectfully requested.

The Claim Amendments

As noted in the Office Action, the claims as-filed included two claims numbered “31”. The second-listed claim 31 as-filed is renumbered to claim 32 and following claims are renumbered accordingly. Renumbered claims 32, 33, and 34 are amended to correct errors in dependency. Claim 27 and renumbered claim 32 are amended to correct obvious scrivener’s errors. Applicants respectfully submit that the present amendments do not introduce new matter into the Application.

Claim Rejections Under 35 U.S.C. § 112, Paragraph Second

Claim 27 was rejected under 35 U.S.C. § 112, ¶2, as allegedly indefinite. Applicants respectfully submit that the present amendments cure any indefiniteness in claim 27 that may have existed. Withdrawal of the rejection is respectfully requested.

Claim 34 was rejected under 35 U.S.C. § 112, ¶2, as allegedly indefinite because of an alleged failure of antecedent basis for limitations recited in those claims. Applicants respectfully submit that it is well-settled that antecedent basis need no be *ipsissimis verbis*. Calling the Office’s attention to page 3, line 26 to page 4, line 9, of the specification, Applicants respectfully submit that the skilled artisan would know what “dipolar aprotic solvent” and “lower alkanol represent”. Applicants further respectfully submit that the present amendments cure any failure of antecedent basis that may have existed.

Claims 28 and 29 were rejected under 35 U.S.C. § 112, ¶2, because, it is alleged, the phrase “in a process” in the preamble of the claims renders the claims vague and indefinite. Because the skilled artisan at the time the application was filed would have been able to

determine, with reasonable certainty, when they were or were not practicing a method that meets the limitations of claims 28 and 29, Applicants respectfully traverse.

The test for definiteness under 35 U.S.C. § 112, ¶2, is whether one skilled in the art would understand what is claimed when the claim is read in light of the specification and be reasonably aware of the scope of the claim. M.P.E.P § 2173.02.

Claim 28 is drawn to a process for making the known chemical entity quetiapine and pharmaceutically acceptable salts thereof. Claim 29 limits the product produced to the hemifumarate salt. Claim 28 recites, *inter alia*, known reactants for making quetiapine and adds limitations to inventive combinations of particular solvents, particular salts, and a phase transfer catalyst.

Thus, claim 28 reads on any process for making quetiapine, or a pharmaceutically acceptable salt thereof, that uses the known reactants, however obtained, but also the inventive process conditions (solvent, PTC, adjuvants) recited in Applicants' claim 28. Claim 29 reads on any such process in which the quetiapine is salified to the hemifumarate salt. Applicants respectfully point-out that breadth of a claim is not equivalent to indefiniteness. M.P.E.P. § 2173.04. Because the skilled artisan making quetiapine hemifumarate using 11-piperazinyl dibenzo[*b,f*]-[1,4]thiazepine hydrochloride and 2-(2-chloroethoxy)ethanol could easily determine when they were or were not doing so by a method that meets the limitations of claim 28, Applicants respectfully submit that the rejection of claim 28 should be withdrawn.

Claim 29 depends from claim 28 and limits the pharmaceutically acceptable salt to the hemifumarate salt. Accordingly, Applicants respectfully submit that claim 29 is likewise definite and that the rejection of claim 29 should also be withdrawn.

Conclusion

Applicants respectfully submit that, based on the foregoing amendments, claims 27, 28, and 34 are in condition for allowance, which allowance is earnestly solicited. If, in the opinion of the Examiner, a telephonic discussion would advance prosecution of the Application, the Examiner is invited to call the undersigned attorney.



U.S.S.N. 10/785,244

REQUEST FOR EXTENSION OF TIME

Applicants respectfully petition under 37 C.F.R. § 1.136 for an extension of time to reply of three months. The petition fee due therefor under 37 C.F.R. § 1.17(a)(3) is paid herewith.

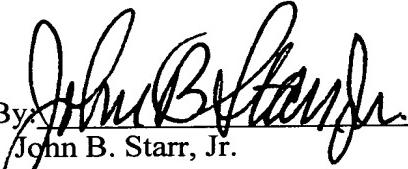
AUTHORIZATION TO DEBIT

The Commissioner is hereby authorized to debit Deposit Account **11-0600** in the amount of for the fees due with this paper. Applicants respectfully submit that no additional fees are due with this paper. If additional fees are due with this paper, the Commissioner is authorized to debit deposit account **11-0600** for such additional fees.

Respectfully submitted,

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December 6, 2005

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